



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/659,683	09/11/2000	Rajnikant Patel	07164.0004-02	9148

22852 7590 03/07/2003

FINNEGAN, HENDERSON, FARABOW, GARRETT &
DUNNER LLP
1300 I STREET, NW
WASHINGTON, DC 20006

EXAMINER

WRIGHT, SONYA N

ART UNIT	PAPER NUMBER
----------	--------------

1626

17

DATE MAILED: 03/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/659,683

Applicant(s)

PATEL, RAJNIKANT

Examiner

Sonya Wright

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

This is a response to Applicant's remarks filed 12-31-02. Claim 13 is pending in this application. The rejection of 35 U.S.C. 102 has been maintained.

Claim Rejections - 35 USC § 102

I. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Robertson et al., US Patent 5,399,574. Applicant claims (S)-4-[[3-[2-(dimethylamino)ethyl-1H-indole-5-yl]methyl]-2-oxazolidinone. On page 1 of the specification Applicant discloses that this compound is also known as (S)-N,N-dimethyl-2-[5-(2-oxo-1,3-oxazolidin-4-yl-methyl)-1H-indol-3-yl]ethylamine, and that it is useful for the treatment of migraine. Robertson et al. teach the instant compound in species examples in column 28, lines 21-22 and lines 44-45, and column 29, lines 6-7. Robertson et al. also teach that their compound is useful in the treatment of migraine in column 1, line 8.

The examiner assumes that the compound of Robertson et al. is non-solvated and pure absent a showing to the contrary. A compound, by default, if not explicitly named to have solvent, is a non-solvated compound. Please note column 28, lines 29-32, where the disclosure indicates the non-solvated nature of the compounds of Robertson et al.. Column 28, lines 29-32 describes that a solid was suspended in HCL

aq., refluxed, diluted with water and filtered. "The classic definition of purity is that a sample of a chemical compound is pure when it contains molecules of only one kind" (see Physics and Chemistry of the Organic Solid State Sloan, p. 181, lines 4-6, attached). Based on this definition, the disclosure of Robertson et al., in column 28, lines 29-32 meets the "pure" requirement of the claim. Additionally, at column 29, lines 15-18, the compound has been further purified to a level of NMR pure. Therefore, every element of the claim is met and anticipation is found.

Response to Arguments

Applicant's arguments filed 12-31-02 have been fully considered but they are not persuasive. Applicant argues that the Examiner has not shown a pure, non-solvated form of the compound in any reference. Applicant argues that Robertson et al. does not use the words "pure" or "non-solvated." Applicant further argues that the Examiner does not refer to any reference document, teaching or facts within her own knowledge to substantiate a rule stating that a compound "by default, if not explicitly named to have solvent, is a non-solvated compound". Applicant argues that Robertson et al. does not describe any level of purity and Robertson et al. does not describe the purpose of the process steps e.g., to reach a certain purity level. Applicant further argues that in the absence of some teaching in the prior art that the mere mention of a compound refers to it having a certain level of purity or being non-solvated, Applicant submits that the Examiner has not established the "pure, non-solvated" element of the instant claim.

Applicant argues that with respect to the process steps on column 28, lines 29-32, more is needed than just the recitation of the dilution and filtered steps provided. That is, the Examiner implies that the steps recited by Robertson et al. will achieve a "pure" and/or "non-solvated" sample. Applicant argues that with respect to language at column 29, lines 15-18, the Examiner shows no teaching that a NMR sample is at a certain degree of purity. Applicant respectfully submits that Robertson et al. does expressly refer to any pure, much less non-solvated, compound. Applicant further submits that the mere mention of a compound does not, in the context set forth in the references, by default refer to the pure compound.

In Applicant's specification, on page 1, lines 20 and 21, Applicant admits that Robertson describes the compound (S)-4-{{3-[2-(dimethylamino)ethyl]-1H-indol-5-yl)methyl}-2-oxazolidinone in WO91/18897, which is the international application published under PCT that relates to US Patent 5,399,574. In addition to teaching the compound, Robertson et al. in fact teach the non-solvated nature of the compounds in column 28, lines 29-32, wherein Robertson et al. teach purification of a solid wherein a solid was suspended in HCl aq., refluxed, diluted with water and filtered. Further, the compounds of Robertson et al. meet the definition of "pure" given in Physics and Chemistry of the Organic Solid State Sloan, p.181, lines 4-6 which is that the compound contains "molecules of only one kind". At column 29, lines 15-18, the compound of Robertson et al. has been further purified to a level of NMR pure, meaning that the compound is pure enough to be analyzed using NMR.

Applicant has provided only general guidance in the specification regarding what is meant by "non-solvated" or "pure". Applicant gives only general information regarding the non-solvated and pure compound on page 9, by stating on page 9, line 23 that "the resulting product is a non-solvated solid of high purity". Applicant has not shown experimental evidence to support Applicant's position that the instant compound is patentable over the compound of Robertson et al. Therefore, every element of the claim is met and anticipation is found.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

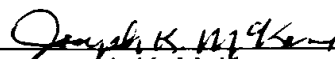
When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

Application/Control Number: 09/659,683
Art Unit: 1626

Page 7



Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

February 28, 2003